

Message Text

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PAGE 01 STOCKH 01543 080743Z
ACTION HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-06 EB-08 /033 W
-----082038Z 117721 /43

R 071545Z APR 77
FM AMEMBASSY STOCKHOLM
TO SECSTATE WASHDC 0285

UNCLAS STOCKHOLM 1543

DEPARTMENT FOR FDA

E.O. 11652: N/A
TAGS: TBIO, SW
SUBJECT: LAETRILE (AMYGDALIN)

REF: STATE 049069

1. THE SWEDISH BOARD OF HEALTH AND WELFARE INFORMED US THAT LAETRILE (AMYGDALIN) IS NEITHER SOLD NOR PROMOTED AS A CANCER CURE IN SWEDEN. THE SUBSTANCE IS NOT OFFERED FOR OTHER USES ACCORDING TO THE NATIONAL FOOD ADMINISTRATION.

2. THE PHARMACEUTICAL DIVISION OF THE NATIONAL BOARD OF HEALTH AND WELFARE CONTROLS THE SELECTION, CLINICAL TESTING, AND LICENSING OF PHARMACEUTICALS. THE FOLLOWING INFORMATION, TRANSLATED FROM THE DIVISION'S ACTIVITIES REPORT, IS IN RESPONSE TO PARAGRAPH 3, REFTEL: (A) PROGRAM FOR THE SELECTION OF PHARMACEUTICALS. BEFORE A PHARMACEUTICAL CAN BE MARKETED IN SWEDEN, IT MUST, ACCORDING TO THE PHARMACEUTICAL ORDINANCE, BE REGISTERED AS A PHARMACETIC SPECIALTY. REGISTRATION MAY NOT TAKE PLACE UNLESS THE SPECIALTY HAS BEEN FOUND ADAPTED TO ITS PURPOSE AND FULFILLS THE GIVEN DIRECTIONS. (B) CLINICAL TESTS. IN ORDER TO REGISTER AS A SPECIALTY (PRODUCT), IT IS REQUIRED THAT, AMONG OTHER THINGS, THE PREPARATION HAS BEEN TESTED CLINICALLY WITH RESPECT TO PROPERTIES AND POSSIBLE SIDE EFFECTS. THE TEST SHALL BE REPORTED TO THE PHARMACEUTICAL DIVISION (PHARMACO-THERAPEUTIC UNCLASSIFIED

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UNIT), WHICH ASSESSES THE TEST WITH RESPECT TO DESIGN AND SAFETY. THE DEPARTMENT'S PHARMACOLOGICAL UNIT TAKES PART IN THE ASSESSMENT OF EARLIER CONDUCTED ANIMAL EXPERIMENTS WITH THE PHARMACEUTICAL IN QUESTION. THE PHARMACEUTICAL DIVISION HAS TO EXPRESS AN OPINION ON THE APPLICATION FOR CLINICAL TESTS WITHIN 14 DAYS, OTHERWISE THE TESTS CAN BE STARTED. THIS FACT MEANS THAT, IF THE PHARMACEUTICAL DIVISION IS TO MAINTAIN CONTROL OVER THESE

CLINICAL TESTS, THE CASES MUST BE HANDLED WITHIN A TWO-WEEK PERIOD AND ANY BACKLOG CANNOT THEREFORE BE ALLOWED. (C) LICENSES. PHARMACEUTICALS WHICH ARE IN THE DEPARTMENT'S FILES (BALANS) AS REGISTRY CASES, OR THOSE FOR WHICH ONE HAS REQUESTED DEREGISTRATION, CAN BE SOLD WITH A LICENSE, THAT IS, DOCTORS ASK TO PRESCRIBE A PHARMACEUTICAL FOR CERTAIN PATIENTS. THUS PATIENTS HAVE ACCESS TO PHARMACEUTICALS WHICH ARE NOT FOUND ON THE MARKET AT THE SAME TIME AS THE PHARMACEUTICAL DIVISION HAS CONTROL OVER UNREGISTERED PHARMACEUTICALS WHICH HAVE BEEN PRESCRIBED.
SMITH

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: REPORTS, DRUGS, LAW, TRADE CONTROLS
Control Number: n/a
Copy: SINGLE
Sent Date: 07-Apr-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STOCKH01543
Document Source: CORE
Document Unique ID: 00
Drafter: n/a
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770123-0809
Format: TEL
From: STOCKHOLM
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t19770476/aaaacoaw.tel
Line Count: 73
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 551149a8-c288-dd11-92da-001cc4696bcc
Office: ACTION HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: 77 STATE 49069
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 24-Jan-2005 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2862418
Secure: OPEN
Status: NATIVE
Subject: LAETRILE (AMYGDALIN)
TAGS: TBIO, SW
To: STATE
Type: TE
vdkgvwkey: odbc://SAS/SAS.dbo.SAS_Docs/551149a8-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
22 May 2009
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009